

1. The Claim Objections

Claims 15-19 and 20-21 are objected to under 35 C.F.R. 1.75(c) as being in improper form because a multiple dependent claim should refer to previous claims in the alternative only and may not depend from another multiple dependent claim. Claims 2 and 3 are objected to because they recite the names of microorganisms without any underlining or using italics lettering. Claims 15 and 16 are objected because they depend from non-elected claims.

Applicants have canceled claims 1- 3 and 15-21 and replaced them with new claims 22-40. As amended, the dependency of the new claims is corrected and the names of microorganisms are italicized.

2. The Claims are Directed to Statutory Subject Matter

Claims 1-3 are rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter. According to the Examiner, the claims are drawn to "microorganisms" which read on a product of nature.

Applicant has canceled claims 1-3 and replaced them with new claims which are directed to a "biologically pure culture of a microorganism..." In view of the foregoing amendments to the claims, the rejections under 35 U.S.C. §101 should be withdrawn.

3. The Claims are Definite as Required by 35 U.S.C. §112, Second Paragraph

Claims 15-16 and 17-21 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly to the Examiner, Claim 16 recites the phrase "isolation of this compound" however it is not clear which specific compound is referred to. The Examiner, alleges that claims 15-16 recite the phrase "if appropriate" however it is not clear what this phrase means. The Examiner maintains that the structural formula for compounds I, II, VII and VIII depicted in claims 15, 16 and 21 are incomplete as they lack a methyl group, thus, rendering the claims unclear.

Applicants have canceled claims 15-16 and replaced them with new claims which more particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the claims as amended specify the compounds to be isolated. Further the phrase "if appropriate" has been deleted and a dependent claim has been added that recites the additional step comprising isolation of the specified compound.

With regard to the Examiner's comments concerning the lack of a methyl group on the structural formulas for compounds I, II, VII and VIII, Applicants maintain that it is commonly understood by those of skill in the art, *i.e.*, chemist, that when the atom is not explicitly set forth in the formula that a carbon atom substituted with only hydrogen is indicated. However, Applicants have amended the claims to specify the methyl group.

In view of the foregoing remarks, the rejections under 35 U.S.C. §112, first paragraph should be withdrawn.

4. The Claims are Enabled

Claims 1-3 and 15-21 are rejected under 35 U.S.C. §112, first paragraph.

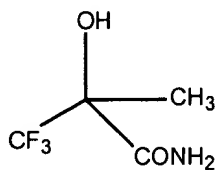
According to the Examiner, the specification is enabling for isolated microorganisms, such as *K. oxytoca* PRS1, *K. Oxytoca* PRS1K17, *R. opacus* ID-622, *A. ramosus* ID620, *Bacillus* sp. ID-621, *K. planticola* ID-624, *K. pneumoniae* ID-625 or *Pseudomonas* sp. (DSM 11355) capable of utilizing (R)-3,3,3-trifluoro-2-hydroxy-2-methylpropionamide (THMP) as its sole source of nitrogen. However, according to the Examiner, the specification does not reasonably provide enablement for claiming any other strain or species of the above microorganisms or any or all microorganisms (including variants and mutants) with the characteristic property of utilizing THMP as sole nitrogen source. The Examiner alleges that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The requirement for enablement can be found expressly stated in the first paragraph of 35 U.S.C. §112, which requires that the disclosure of an invention be "in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same..." *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984).

This rejection is in error and should be withdrawn because the specification does indeed describe methods for isolation of the claimed microorganisms, *i.e.* those having stereospecific amidohydrolase activity, and demonstrates by way of working examples the use of such methods for isolation of the claimed microorganisms. In this regard, the Examiner's

attention is directed to page 2, line 34 through page 3, line 30 of the specification which teaches methods for isolation of the claimed microorganisms and Example 4 of the specification which demonstrates the successful isolation of such claimed microorganisms using the disclosed methods.

While some experimentation may be necessary to isolate the microorganisms of interest and to determine whether such microorganisms possess the desired properties, such experimentation, given the teaching provided by the specification, cannot be deemed undue. Enablement is not precluded even if some experimentation is necessary. *Hybridtech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986). This is so even if the amount of experimentation required is laborious. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Thus the pending claims, covering "microorganisms which are capable of utilizing propionamide of the formula:



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in the form of the racemate or of its optically active isomers as the sole nitrogen source", are fully enabled within the meaning of 35 U.S.C. §112.

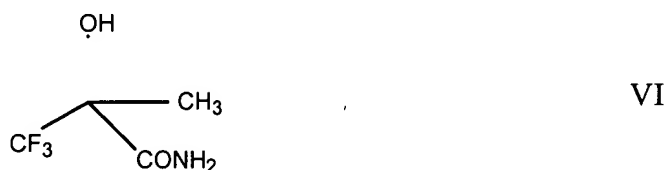
5. The Claims Subject Matter is Described in the Specification as Required
By 35 U.S.C. §112, First Paragraph

Claims 1-3 are rejected under 35 U.S.C. §112, first paragraph. The Examiner alleges that the claimed subject matter was not describe in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

According to the Examiner, the claims are directed to a genus of microorganisms (including variants and mutants) which are capable of utilizing THMP as sole source of nitrogen. However, the specification does not contain any other characteristic feature of the encompassed microorganisms apart from the functional characteristic of the capability of utilizing THMP as sole source of nitrogen. The Examiner maintains that the genus of above microorganisms constitutes an extremely large variable genus with many different capabilities and characteristics. Therefore, many unrelated microorganisms are encompassed within the scope of these claims, including mutants and variants.

Applicants maintain that the specification does indeed describe the claimed microorganisms in such a way as to indicate possession of the invention at the time of filing the application. In this regard, the Examiner's attention is directed to page 1, lines 1-14 of the specification that defines the claimed microorganisms as only those "microorganisms which are capable of utilizing propionamide of the formula:



in the form of the racemate or of its optically active isomers as the sole nitrogen source".

The Examiner's attention is also directed to the fact that Applicants have disclose the isolation of eight different microorganisms having the desired characteristics. The

microorganisms include those of the genus *Rhodococcus*, *Arthrobacter*, *Bacillus*, *Klebsiella* or *Pseudomonas*. Further, four of those eight microorganisms were different species of *Klebsiella*. Given the isolation of not just a single species of microorganisms having the desired characteristics, but rather, the isolation of multiple microorganisms having those specified characteristics, Applicants maintain that the invention is fully described as required by 35 U.S.C. §112, first paragraph. Therefore, the rejections should be withdrawn.

5. Deposit of Microbial Strains Under the Terms
of the Budapest Treaty

Claim 3 is rejected because the invention appears to employ novel microbial strains. The Examiner asserts that since the microbial strains are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed microbial strains have not been shown to be publicly known and freely available.

Attorney of record asserts that that a deposit of the following microorganisms:

Klebsiella oxytoca PRS1 (DSM 11009), *Klebsiella oxytoca* PRS1K17 (DSM 11623),
Rhodococcus opacus ID-662 (DSM 11344), *Arthrobacter ramosus* ID-620 (DSM 11350),
Bacillus sp. ID-621 (DSM 11351), *Klebsiella planticola* ID-624 (DSM 11354), *Klebsiella pneumoniae* ID-625 (DSM 11355) and *Pseudomonas* sp. (DSM 11010) has been made under the Budapest Treaty and that all restrictions imposed by the depositor pertaining to the availability to the public of the deposited material will be irrevocably removed upon issuance of the patents.

CONCLUSION

Entry of the foregoing amendments into the file history of the above-identified application is respectfully requested. Applicants believe that the foregoing amendments and remarks place the claims in condition for allowance. Withdrawal of all rejections and reconsideration of the amended claims is requested.

Respectfully submitted,


Henry Tang

Patent Office Reg. No. 29,705
Attorney for Applicants

Carmella L. Stephens
Patent Office Reg. No. 41,328
Agent for Applicants
(212) 408-2539